REMARKS/ARGUMENTS

A final Office Action was mailed on August 2, 2007. This Office Action rejected all claims 1-20 for failing to comply with the written description requirement under 35 U.S.C. §112. In addition, a new reference, Gates US 5,522,875, was cited in both anticipation and obviousness rejections of various claims.

Claims 1-20 rejected under 35 U.S.C. §112, first paragraph

Claims 1-20 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Office Action states in paragraph 1,

> The limitation "not movable with respect to each other at all times" is lacking support in the original filed application." Applicant argued in the remarks of 5/16/2007 that support for this limitation is provided through the disclosure that the tube "can be drawn over the core by pulling the tube through a die", and that the assembly is quickly quenched, which sets the nitinol outer tube over the core. Applicant further argued that "to set" means to make the core at all times immovable relative to the outer covering. However, the use of a die and quickly quenching speaks nothing to the movability of the core and outer covering because the relationship between the core and outer covering, when coming through the die, could be such that no interference fit exists between the two elements, and there is no disclosure that explicitly or implicitly indicates that such an interference fit exists.... The Examiner is of the position that "to set" does not

necessarily mean to make immovable at all times because in common use, "to set" does not imply movability....

Applicants' specification only discusses and enables a stylet that has an inner core fixed to the outer covering

Applicants respectfully disagree with each of Examiner's responses. The disclosure can only enable three possible embodiments of a stylet: (A) the disclosure enables an embodiment of a final, assembled stylet that has an inner core and outer covering that do not move relative to each other; (B) the disclosure enables an embodiment of a final, assembled stylet that has an inner core and outer covering that can move relative to each other; and (D) the disclosure enables both embodiments (A) and (B).

Applicants contend that their disclosure only discusses and enables case (A). There is no discussion anywhere in Applicants' disclosure of a reason, purpose, advantage or method of using a stylet having an inner core and outer covering, where the inner core is movable with the outer covering in a final, assembled stylet. It is common sense that if such an unusual stylet embodiment were to be included as part of Applicants' invention, that it should be thoroughly discussed.

A stylet having an inner core and outer covering where the inner core is removable is unusual. One skilled in the art understands that a conventional "stylet" is a single, solid piece of wire, made of tungsten or stainless steel. (See Applicants' specification, paragraph [0056].) While, conceivably, a stylet-like assembly could be formed of a stylet having a removable inner core and outer covering, it is instructive that

Applicants' specification is silent and does not discuss anywhere such a deviation from the normal understanding of what a stylet is. Without any discussion of the benefit of having an inner core that is movable from the outer covering, it is reasonable to conclude that Applicants' assembled stylet is similarly solid in its final, assembled form.

Applicants' specification positively teaches that the inner core is fixed relative to the outer covering

Not only is Applicants' specification silent on an embodiment where the inner core is removable from the outer covering, Applicants' specification positively explains and teaches that the inner core is to be fixed relative to the outer covering.

The presence of the handle 50 of the stylet requires that the inner core not be removable from the outer covering. We have already mentioned that the presence of the handle fixed over the proximal end of the stylet makes removability of the inner core from the outer core impractical, if not impossible, in the assembled stylet. If the handle were not fixed to the stylet, thereby making the inner core movable from the outer covering, the handle would not serve its intended purpose.

Moreover, Applicants' specification positively teaches a specific manufacturing process for fixing the outer covering to the inner core. The specification discusses how, "With the core placed inside the tube, the nitinol tube can be drawn over the core by pulling the tube through a die." [Applicants' specification [0052], 3rd sentence.] If the inner core is to be removable, there is no reason to draw the outer covering through a die. There is only one purpose to spend time and energy to draw the outer covering with the core inside – that is to squeeze the outer covering over the

core. If the purpose is to have the core removable from the outer covering, this step is unnecessary.

The Office Action suggests that "set" may not equate with fix or immovable. There are many common meanings for the word "set". One such common meaning is "To become fixed, harden or congeal." (American Heritage Dictionary, Dell Publishing, New York, 1983; also search Google and type – "define: set") One skilled in the art would understand from the context of Applicants' specification and the description of the invention what "set" means. Clearly, "set" as used by Applicant does not mean the kind of "set" in which a box is "set" on a table, where the box is removable from the table. If "set" had that usage chosen by the Examiner, i.e., placed upon and later removable, there would be no reason to draw the outer covering over the inner core through a die. It would be enough (and less costly) merely to place the inner core in the outer covering and do nothing further in the manufacturing steps.

In addition, considered in context, heating and quenching can be performed, in one example of a manufacturing method to make the stylet, to further "set" the outer covering over the inner core, given that this step follows after the steps of (i) placing the inner core in the outer covering and (ii) drawing the outer covering. The Office Action states that it is possible that "quenching could be performed to relax the internal stresses of the metal and not fix them to each other. It may be true that quenching can be used to relax the internal stress of the metal, and not necessarily to fix the core to the outer covering. However, it is a presumptive to believe that the quenching step is only to relax internal stress of the metal --- there is no mention of this advantage or purpose (relaxation of the metal) in the specification. However, it is

instructive that the specification, instead, positively teaches that a reason to undergo the process of heating and quenching is to "set" the outer covering over the inner core, while never mentioning the possibility of relaxation of internal stresses of the metal.

In sum, Applicants' specification is silent on a stylet that has a movable inner core and only discusses and enables an embodiment of the stylet having an inner core that is fixed to the outer covering. In fact, the presence of a stylet handle makes a movable inner core impractical or impossible.

Although Applicants' claim terms are to be given their broadest interpretation, it should be interpreted consistent with the specification. MPEP §2111. The specification never discusses a stylet that has a removable inner core from the outer core. Were the inner core to be removable in one stylet embodiment, the specification should have reasonably espoused the advantages or desirability of such removability. Devoid of any discussion of this unusual stylet embodiment, it is too expansive to assume that Applicants' claims include an embodiment of the stylet, where in its final assembled product, the inner core is removable or separable from the outer covering. When read with the specification, there is no viable interpretation of the claims except stylet embodiment (A). As such, Applicants' claims, even as originally filed, cannot be expansively read to include an embodiment where the inner core is movable with respect to the outer covering. Understanding the ordinary meaning of a "stylet", as being usually a solid, single piece, Applicants' claims would be understood by those skilled in the art to be a stylet that is comprised of composite material, but still a single piece in a final, assembled form. Hence, Applicants' specification clearly enables, under §112, a stylet that has an inner core that is immovable relative to the

outer covering. For the foregoing reasons, it is believed that the §112 rejection of claims 1-20 is overcome.

As a final matter, the Examiner objected to the use of "at all times" as lacking support and even contradicted by the disclosure. Applicants respectfully disagree with this conclusion. The "at all times" necessarily describes the final, assembled, stylet and not the intermediate, temporary, state of the stylet during manufacture. It should be no matter that during manufacturing of the stylet, the inner core and outer covering are temporarily movable. In any case, it is also believed that "at all times" adds nothing substantive to the claims that is not already in the claims, since the claims should never have been read expansively to encompass a stylet embodiment where the inner core is movable with respect to the outer covering. As such, the phrase "at all times" has been deleted in independent claims 1, 14 and 18.

Applicants believe that support does exist in Applicants' specification for a stylet where the inner core is immovable from the outer covering and is positively described. Thus, the §112 rejection of each claim 1-20 is overcome.

Claims 1-10, 13- 18 and 20 are rejected under 35 U.S.C. §102(b), as anticipated by Gates et al.

Claims 1-10, 13-18 and 20 were rejected as anticipated by Gates et al (U.S. 5,522,875, hereinafter "Gates"). Applicants traverse this rejection. Gates has an external wound coil, which has mechanical gaps between adjacent parts of the coils. The wound coil, formed as a covering, is not physically continuous throughout the covering because it has mechanical separation between adjacent windings, and

separates even further when bent. Applicants' independent claims 1, 14, and 18 have been amended to clarify that "the outer covering includes a layer which is constructed to be physically continuous throughout the layer, with no mechanical separation anywhere in the layer."

No new matter has been added. Support for this amendment is found in various parts of Applicants' specification, including Figures 3, 4 and 5 which are cross-sectional and longitudinal, sectional views showing that the outer covering 20 and 20' is a layer that is physically continuous throughout, with no mechanical separation anywhere in the layer. When a reference is missing an element of the claim, it cannot anticipate the claim. Because Gates is missing an outer covering that is not physically continuous throughout, it does not anticipate any of Applicants' amended independent claims 1, 14 and 18 and, by dependency, the dependent claims 2-10 and 13, 15-17 and 20. Applicants have not discussed separate reasons for dependent claims that distinguish from Gates, but reserve the right to discuss these reasons in the future.

Claim 11, 12, 15 and 19 were rejected under 35 U.S.C. §103(a)

Claims 11, 12, 15 and 19 were rejected under 35 U.S.C. §103(a) as obvious over Gates. Applicants traverse this rejection. Gates specifically teaches that coil windings be used. Gates' stylet design is quite different from Applicants' stylet design, which avoids the use of coil windings. As such, Gates does not make obvious Applicants' invention and claims, which encompasses a stylet design that specifically does not employ coil windings for the outer covering. As such, Applicants' independent claims 1, 14 and 18 are not obvious in view of Gates. By dependency, dependent

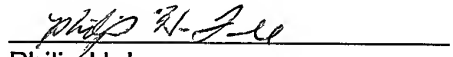
claims 11, 12, 15 and 19 are also not made obvious by Gates. Applicants have not discussed other reasons in the dependent claims, which separately would make each claim not obvious in view of Gates. We reserve the right to discuss such other reasons in future prosecution.

Conclusion

No fee is believed due with this response. However, if any fees are due, please charge any required fees to Deposit Account Number **50-0648**.

An early indication of allowability of pending claims 1-20 is respectfully requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,



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